

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 157-294 are pending in the application, with claims 157, 180, 203, 214, 229, 243, 252, 264, 280 and 288 being the independent claims. Claims 24-39, 43-100, 105-139 and 141-156 are cancelled without prejudice to or disclaimer of the subject matter therein. New claims 157-294 are added. Support for the claims can be found throughout the specification and original claims. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Applicants point out that new claims 203-206, 209, 213, 243-246, 249, 252, 254-256, 259, 263-266, 267 271, 272, 275, 279 and 253 correspond to allowed claims 75-78, 80, 83, 121-124, 126, 128, 129-131, 133, 136-139, 141, 142, 143, 145, 148 and 156, respectively.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112

Written Description

Claims 24, 51, 105, 107, 111, and their dependent claims were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Specifically, the Examiner alleged that the specification does not suggest that a polypeptide with up to 10% of its amino acids substituted would retain the property of inducing antibodies that would also bind the complete polypeptide. Applicants respectfully traverse this rejection.

Solely to expedite prosecution, Applicants have canceled claims 24, 51, 105, 107 and 111, and the claims dependent therefrom, and have added claims 157-294. None of the added claims recite the limitation that the nucleic acid encode an antibody capable of inducing particular antibodies. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 46, 48, 70, 72, 79, 81, 116, 118, 125, 127, 132, 134, 144, 146, and claims dependent therefrom were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description for the recitation of "heterologous regulatory sequence." Applicants have cancelled these claims and have added claims 157-294. None of the added claims contain the recitation "heterologous regulatory sequence." Accordingly, withdrawal of this rejection is respectfully requested.

Enablement

Claims 24-26, 28, 29, 31, 32, 34, 35, 37, 38, 40, 41, 43-53, 55, 56, 58, 59, 61, 62, 64, 65, 67-74, 105, 107, 109, 111 and 113-120 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. The Examiner states that "the rejection is directed to a lack of enablement for *using* the claimed polynucleotides." Paper No. 31, page 5. Applicants have cancelled claims 24-26, 28, 29, 31, 32, 34, 35, 37, 38, 40, 41, 43-53, 55, 56, 58, 59, 61, 62, 64, 65, 67-74, 105, 107, 109, 111 and 113-120 and have added claims 157-294. Applicants respectfully traverse this rejection as it may be applied to the new claims.

The polynucleotides of the pending claims are useful for, *inter alia*, for diagnosis of prostate cancer and/or regulation of Prostate-Specific Antigen (PSA) expression.

A polynucleotide which is 90% identical to SEQ ID NO:1, for example, as recited in claim 157, is useful to detect SEQ ID NO:1 expression, regardless of whether or not the variant encodes a polypeptide. This is because of the high level of identity between the two molecules. As disclosed in the specification, detection of SEQ ID NO:1 expression is useful, *inter alia*, as a prostate-specific tumor marker.

Additionally, Applicants have provided, at page 8, lines 29-31, the regions which contain conserved amino acids. Applicants have also provided at Example 31 and Figures 8-10, the results of experiments with PDEF polypeptides which are less than 100% identical to SEQ ID NO:2. These experiments show that several different PDEF variants interact with the androgen receptor. Thus, one of ordinary skill in the art would know how to use a polynucleotide of the claims, including polynucleotides encoding fragments of SEQ ID NO:2 as well as polynucleotides encoding amino acid sequences which are a particular percent identical to SEQ ID NO:2 or fragments thereof, to make a polypeptide which is less than 100% identical to SEQ ID NO:2 to regulate PSA expression.

Applicants submit that the claims are fully enabled. Accordingly, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 24, 28, 29, 43-48, 50, 51, 55, 56, 67-72, 74, 84, 99, 100, 105, 107, 113-118, and 120 were rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by GenBank Accession No. AA930371 (Ref. AR12 of IDS filed February 11, 1999, hereinafter AR12).

Applicants have cancelled the rejected claims and have added claims 157-294. None of the added claims read on the art cited by the Examiner. Accordingly, withdrawal of this rejection is respectfully requested.

Double patenting

Claims 54, 57, 60, 63, and 66 would be objected to under 37 C.F.R. 1.75 for double patenting if claims 27, 30, 33, 36, and 39 would be found allowable. Applicants have cancelled claims 27, 30, 33, 36, 39, 54, 57, 60, 63 and 66, and have added claims 157-294. None of the added claims are of the same scope as any of the other added claims. Accordingly, withdrawal of this rejection is respectfully requested.

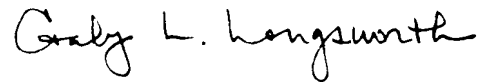
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

Claims 24-156 were cancelled.

New claims 157-294 were added.